UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT KNOXVILLE

UNIVERSITY OF PITTSBURGH, Plaintiff, v. DAVID W. TOWNSEND; RONALD NUTT; CTI MOLECULAR IMAGING, INC.; and CTI PET SYSTEMS, INC., Defendants.	)	No. 3:04-cv-291 (Phillips/Shirley)

MEMORANDUM AND ORDER

This matter is before the undersigned pursuant to 28 U.S.C. § 636(b), the Rules of this Court, and by Order [Docs. 83, 86] of the Honorable Thomas W. Phillips, United States District Judge, for disposition of the defendants' motions to exclude the testimony of the plaintiff's experts Robert Wooldridge, Thomas Lewellen, and Mark Gleason [Doc. 77, 79, 81] and the defendants' motion to exclude testimony based on spoliation of evidence [Doc. 84]. The Court held a Daubert hearing on February 27 and 28, 2007. Participating on behalf of the plaintiff were attorneys David G. Oberdick, Andrew R. Tillman, and Dwight E. Tarwater. Participating on behalf of the defendants were attorneys Daniel F. Diffley, Randall L. Allen, and J. Chadwick Hatmaker.

INTRODUCTION

In this action, the plaintiff University of Pittsburgh ("University") alleges that the defendants David W. Townsend, Ronald Nutt, CTI Molecular Imaging, Inc., and CTI PET Systems,

Inc. (collectively, the "defendants"), subverted and misappropriated the University's rights and interests in valuable medical scanning technology, namely a combined PET/CT scanner, that the University alleges was developed collaboratively at its campus over the course of several years. The University alleges that the defendants' wrongful actions include breaches of, and interference with, the University's contractual rights to joint ownership in the technology as well as tortious misrepresentations and misappropriation. [Doc. 31, Amended Complaint at ¶1]. The University alleges that its ownership rights and interests include, but are not limited to, the inventions described in U.S. Patent No. 6,490,476 ("'476 patent") and U.S. Patent No. 6,631,284 ("'284 patent"), as well as the broader intellectual property, technology, development, and operational know-how associated with the PET/CT scanner; the attenuation correction methodology and related algorithms software programs/code utilized in the PET/CT scanner; and the PET/CT scanner test data generated at the University and utilized by the defendants. [Id. at ¶136].

DEFENDANTS' MOTION TO EXCLUDE BASED ON SPOLIATION OF EVIDENCE

The defendants move the Court to exclude from trial any and all testimony of the plaintiff's proposed experts Robert Wooldridge and Thomas Lewellen based on the spoliation and destruction of evidence. Specifically, the defendants allege that Wooldridge and Lewellen, along with the plaintiff's counsel, admittedly destroyed copies of e-mails between these experts and counsel, and that the witnesses also destroyed previous drafts of their expert reports. The defendants argue that as a result of this spoliation, they have been unfairly prejudiced and denied the opportunity to cross-examine these witnesses as to counsel's contributions to their expert reports.

I. Factual Background

In their First Request for Production of Documents served on February 10, 2005 [Doc. 85 Ex. F], the defendants requested the plaintiff produce "[a]ll [d]ocuments provided to or by [y]ou to, revised by, relied upon, or otherwise used in consultation with or as a basis for consultation with, any expert witness identified by [y]ou pursuant to Fed. R. Civ. Proc. 26(a)(2)." In its response served on April 8, 2005 [Doc. 85 Ex. G], the plaintiff objected to this request as premature and stated that "[r]esponsive documents will be produced in accordance with Federal Rule of Civil Procedure 26(a)(2) and the Case Management Order applicable to this matter."

In a subpoena issued to Robert Wooldridge on July 27, 2006 and commanding him to appear for deposition on August 7, 2006, the following document requests were made:

1. All documents reviewed by you or anyone that assisted you in connection with preparing your Expert Report.
2. Any and all documents that you relied upon in preparing your Expert Report.
3. All drafts of the Expert Report.
4. All notes made by you or anyone that assisted you during the preparation of your Expert Report.
5. All correspondence between you and any other individual, including, but not limited to counsel for the University of Pittsburgh related to the Expert Report.
6. All documents provided to you by counsel for the University of Pittsburgh or any other representative of the University of Pittsburgh in connection with the preparation of your Expert Report.
7. All documents contained within your files related in any way to the preparation of your Expert Report.

[Doc. 85 Ex. A]. A subpoena with identical document requests was issued on July 28, 2006 for Thomas Lewellen's deposition on August 16, 2006. [Id.].

In his deposition on August 7, 2006, Wooldridge testified that he had not retained previous drafts of his report, as he worked only from one draft. He testified that he had e-mailed earlier drafts of his report to plaintiff's counsel and that counsel e-mailed it back to him with revisions. Wooldridge testified that counsel added Bates numbers, corrected some typographical errors, added two footnotes (on pages 10 and 28) of legal citations to the report, and asked him if he agreed with those revisions. Wooldridge admitted that he had not read the legal authority cited in the footnotes. He testified that he did not keep copies of these emails from counsel. [Doc. 77 Ex. B at 174-77]. At the Daubert hearing, Wooldridge reiterated that the comments he received from counsel were stylistic and not substantive in nature.

At his deposition on August 16, 2006, Lewellen testified that he too only had one working draft of his report and that he did not retain drafts of his report. He testified that he received e-mail communications from counsel, and that any documents he received via e-mail were retained. Lewellen recalled receiving "marked up" versions of his draft report from plaintiff's counsel via e-mail but did not retain copies of these drafts. He also recalled receiving some comments back from plaintiff's counsel via e-mail. He did not retain the e-mails themselves, upon the suggestion of plaintiff's counsel. [Doc. 79 Ex. B at 29-32]. At the Daubert hearing, Lewellen testified that the comments he received from counsel were mainly editorial comments regarding style. Substantively, Lewellen testified that counsel suggested removing one section regarding Lewellen's opinions on disclosure of conflicts, as this was not a contested issue in the litigation, and requested that Lewellen address an additional question regarding Dr. Meltzer's involvement in the PET/CT scanner project.

In subsequent correspondence between counsel, defendants' counsel requested copies of the e-mails between these experts and plaintiffs' counsel, as well as copies of any prior drafts of their reports. Plaintiff's counsel advised that he had not retained any of these e-mails or drafts and that it was counsel's practice to instruct experts not to retain copies of such drafts. [Doc. 85 Exs. B, C, D].

II. Analysis

The defendants argue that draft expert reports and communications between experts and counsel are discoverable pursuant to Rule 26(a)(2) of the Federal Rules of Civil Procedure. The defendants further contend that Rule 26(a)(2) imposes an affirmative duty upon an expert "to preserve all documents, including e-mails and drafts of a report." [Doc. 85 at 5]. The defendants contend that because the plaintiff's experts and counsel destroyed discoverable evidence, the plaintiff should be sanctioned by precluding Lewellen and Wooldridge from testifying at trial.

The plaintiff contends that the defendants' accusations of spoliation and destruction of documents must be summarily disregarded. Specifically, the plaintiff argues that until the subpoenas were served on the plaintiff's experts shortly before their depositions, there was no outstanding discovery request asking for the drafts of any expert reports, and that no documents were destroyed once the subpoenas were served. Further, the plaintiff contends that the requested email communications and draft reports are not "evidence" and raise inherent issues of privilege and work product. Finally, the plaintiff argues that the defendants have not suffered any prejudice because they have had the opportunity to fully depose the plaintiff's experts and the experts have

specifically identified the portions of their reports where they received assistance or input from counsel.

"Spoliation is the intentional destruction of evidence that is presumed to be unfavorable to the party responsible for the destruction." McDaniel v. Transcender, LLC, 119 Fed. Appx. 774, 782 (6th Cir. Jan. 31, 2005). The rules defining spoliation of evidence and the appropriate sanctions therefor are determined by state law, in this case, Tennessee. Id. (citing Nationwide Mut. Fire Ins. Co. v. Ford Motor Co., 174 F.3d 801, 804 (6th Cir. 1999)). As a general rule, Tennessee law states that spoliation of evidence creates a rebuttable presumption that the destroyed evidence would have been unfavorable to the offending party. McDaniel, 119 Fed. Appx. at 782 (quoting Thurman-Bryant Elec. Supply Co. v. Unisys Corp., No. 03A01-CV-00152 (Tenn. Ct. App. Mar. 16, 1992)). This inference arises, however, only where the spoliation was intentional, fraudulent, and done with a "desire to suppress the truth." Id.

Contrary to the defendants' assertion, the Court does not read Rule 26(a)(2) to impose an "affirmative duty" upon an expert to preserve "all documents," particularly report drafts, and the defendants do not cite any support for such a sweeping obligation. Nor does Rule 26(a)(2) require that draft reports be disclosed as part of an expert disclosure. See Fed. R. Civ. P. 26(a)(2)(B) ("The report shall contain a complete statement of all opinions to be expressed and the basis and reasons therefor; the data or other information considered by the witness in forming the opinions; any exhibits to be used as a summary of or support for the opinions; the qualifications of the witness, including a list of all publications authored by the witness within the preceding ten years; the compensation to be paid for the study and testimony; and a listing of any other cases in which the witness has testified as an expert at trial or by deposition within the preceding four years."). While

not technically a required subject of disclosure, and contrary to the plaintiff's arguments, draft reports are certainly discoverable, and the defendants contend that they requested any and all expert report drafts in their February, 2005 discovery requests. This discovery request, however, is far from the model of clarity. The request seeks the production of "[a]ll [d]ocuments provided to or by [y]ou to, revised by, relied upon, or otherwise used in consultation with or as a basis for consultation with, any expert witness . . . ." Even if this awkwardly worded request could be construed to require production of draft reports (and the Court finds it does not), the Court finds that this request, served well over a year prior to the date that any expert disclosures were required to be made, to be an unreasonable request, essentially imposing a continuing obligation on a party to disclose any document from an expert – whether it be a letter or a draft report – as it is received through the consultation process. Such a requirement would virtually nullify the expert disclosure deadline established by the Court.

The defendants did make a clear request for drafts of expert reports in their subpoenas to Wooldridge and Lewellen. Only at that point were the experts under a duty to retain any drafts and produce them at their depositions. It appears from the representations of counsel and the testimony of Wooldridge and Lewellen at the Daubert hearing that by the time that the subpoenas were served, any draft reports that had existed (by virtue of being attached to e-mails sent back and forth between counsel and the experts) had already been destroyed. Because the draft reports were destroyed prior to the creation of any obligation on the part of the experts, the plaintiff or the plaintiff's counsel to retain them, the Court finds that the destruction of these draft reports was not done intentionally, fraudulently, and with "a desire to suppress the truth," and therefore, is not sanctionable.

With respect to the experts' communications with counsel, Rule 26(a)(2) does require an expert report to contain "the data or other information considered by the witness in forming the opinions." Thus, to the extent that correspondence from counsel may contain such "data or other information," such as factual background or factual assumptions to be made by the expert in forming his or her opinions, such correspondence must be disclosed. The Advisory Committee Notes make clear that such information, even though provided by counsel, is not immune from disclosure by any privilege or work production protection:

> The report is to disclose the data and other information considered by the expert and any exhibits or charts that summarize or support the expert's opinions. Given this obligation of disclosure, litigants should no longer be able to argue that materials furnished to their experts to be used in forming their opinions – whether or not ultimately relied upon by the expert – are privileged or otherwise protected from disclosure when such persons are testifying or being deposed.

1993 Advisory Committee's Notes to Fed. R. Civ. P. 26. The Sixth Circuit recently reiterated this principle in Regional Airport Authority of Louisville v. LFG, LLC, 460 F.3d 697, 717 (6th Cir. 2006), holding that "Rule 26 creates a bright-line rule mandating disclosure of all documents, including attorney opinion work product, given to testifying experts."

Thus, to the extent that plaintiff's counsel communicated with Wooldridge and Lewellen, such communications were required to be disclosed pursuant to Rule 26(a)(2)(B) if the communications provided information or other data to be considered by the expert in forming his opinions. While communications that did not furnish information or data to be considered by the expert may not have been required to be disclosed, given the lack of attorney-client privilege or

work product protection to these communications, any correspondence or communication between counsel and the experts was, at the very least, discoverable.

The subject e-mails were the target of multiple discovery requests, namely the defendants' February, 2005 request for production and the 2006 subpoenas to the experts. The Court finds that it was improper for plaintiff's counsel to have instructed and/or otherwise suggested to the experts that such communications should be destroyed. The Court notes that plaintiff's counsel has acknolwedged this error and has apologized to the Court and opposing counsel.

Although the Court finds that counsel acted improperly in destroying these communications in light of the pending discovery requests, the Court does not find that this action was done with any fraudulent intent. Accordingly, the Court will not, in its discretion, impose any sanctions on the plaintiff. The Court finds that the defendants have not been prejudiced by the destruction of these communications, as the defendants have been able to fully cross-examine the witnesses, both during depositions and at the Daubert hearing, on the substance of these communications and particularly, counsel's input into their respective reports. Further, the Court notes that any prejudice that might have incurred (essentially depriving the defendants of a document with which to cross-examine and possibly impeach these experts) is minimal, given the collateral nature of this issue. The Court declines to impose such harsh sanctions as the wholesale exclusion of an expert for an infraction of this nature. For the foregoing reasons, Defendants' Motion to Exclude Expert Testimony Based on Spoliation of Evidence [Doc. 84] is **DENIED**.

DEFENDANTS' DAUBERT MOTIONS

The defendants have filed several motions challenging the qualifications and/or opinions of the plaintiff's expert witnesses under Rule 702 of the Federal Rules of Evidence and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

The trial judge must act as a gatekeeper, admitting only that expert testimony that is relevant and reliable. Daubert, 509 U.S. at 589. With regard to scientific knowledge, the trial court must initially determine whether the reasoning or methodology used is scientifically valid and is properly applied to the facts at issue in the trial. Id. To aid the trial court in this gatekeeping role, the Supreme Court has listed several key considerations: (1) whether the scientific knowledge can or has been tested; (2) whether the given theory or technique has been published or been the subject of peer review; (3) whether a known error rate exists; and (4) whether the theory enjoys general acceptance in the particular field. Id. at 592-94. The Court's focus "must be solely on principles and methodology, not on the conclusions that they generate." Id. at 595. "[T]he test under Daubert is not the correctness of the expert's conclusions but the soundness of his methodology." Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1318 (9th Cir. 1995).

Although Daubert centered around the admissibility of scientific expert opinions, the trial court's gatekeeping function applies to all expert testimony, including that based upon

specialized or technical, as opposed to scientific, knowledge. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 147-48 (1999); Berry v. City of Detroit, 25 F.3d 1342, 1350 (6th Cir. 1994). The trial court's objective "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire, 526 U.S. at 152. The trial judge enjoys broad discretion in determining whether the factors listed in Daubert reasonably measure reliability in a given case. Id. at 153. The Sixth Circuit has recognized that the enumerated Daubert factors "may be of limited utility in the context of non-scientific expert testimony," as opinions formed based upon personal knowledge or practical experience "do not easily lead themselves to scholarly review or to traditional scientific evaluation." First Tennessee Bank Nat'l Ass'n v. Barreto, 268 F.3d 319, 334, 335 (6th Cir. 2001); see also Surles v. Greyhound Lines, Inc., 474 F.3d 288, 295 (6th Cir. 2007) (noting that "the factors enumerated in Daubert cannot readily be applied to measure the reliability of" testimony based upon "technical or other specialized knowledge"). With this framework in mind, the Court will now address each of the defendants' motions.

I. Robert Wooldridge

The defendants move to exclude the proposed testimony of the University's expert, Robert Wooldridge. [Doc. 77].[1] Wooldridge has been with Center for Technology Transfer and

[1]In their motion, the defendants also move to exclude Wooldridge's testimony on the grounds that he did not retain copies of his draft reports or copies of his e-mail correspondence with plaintiff's counsel. The Court already has addressed this basis for exclusion in disposing of the defendants' motion to exclude testimony based on spoliation of evidence [Doc. 84] and therefore will not address this argument further.

Enterprise Creation at Carnegie Mellon University since 1996 and has served as its Director since 2002. [Exhibit 5A Attach. 1, Wooldridge C.V.]. That office solicits invention disclosures from Carnegie Mellon's faculty, processes them through the University's policies and procedures, evaluates the technologies for their suitability as commercial products, and advises faculty on how to commercialize the technology. Wooldridge has been involved in the negotiation of over 400 license agreements. In the course of his employment with Carnegie Mellon, Wooldridge has worked regularly with the requirements of the Bayh-Dole Act and the accompanying federal regulations. [Wooldridge Daubert Testimony at 18-19]. He has also had experience in applying university policies concerning intellectual property and conflicts of interest. He is a member of the Licensing Executive Society and the Association of University Technology Managers ("AUTM"). He has attended courses through AUTM regarding technology transfer, attends annual AUTM meetings, and has given presentations on technology transfer issues. He also serves as the Chair of the AUTM software course. [Id. at 20-22].

Wooldridge offers four primary opinions in his report. First, Wooldridge opines that the University of Pittsburgh has ownership rights in the two issued patents and pending patent application relating to the commercial PET/CT scanner, as well as the general know-how concerning the combined PET/CT scanner that was developed by University personnel and test data derived from the use and operation of the combined PET/CT scanner at the University. Second, he opines that university technology transfer offices typically engage in licensing agreements to reflect the value provided by university employees and/or through university facilities in connection with the development of commercialized technology. While not assessing a license value for the University's interest, Wooldridge goes on to discuss some typical financial terms that would appear

in such licenses and opines that a royalty rate from 2% to 4% would be within a reasonable range. Third, Wooldridge opines that the University acted consistently with standard technology transfer policies in dealing with the defendants and in its efforts to protect the University's intellectual property rights in the combined PET/CT scanner technology. Fourth, Wooldridge opines that the University's intellectual property rights in the combined PET/CT scanner under the Bayh-Dole Act are not affected by the timing of its invention disclosure to the NIH and election of title in November, 1999, and further, that the prior consulting and intellectual property assignment agreement between Dr. Townsend and CPS would not affect the University's intellectual property rights, as the Bayh-Dole Act supersedes and nullifies any intellectual property assignment rights and obligations created under the consulting agreements. [Wooldridge Report at 3-5].

A. Ownership Rights

With respect to Wooldridge's opinions regarding the University's ownership rights, the defendants argue that Wooldridge is not qualified to offer opinions on the law, and further, that his opinions amount to little more than legal conclusions. Even if Wooldridge is somehow qualified, the defendants argue, his opinions regarding ownership are not based on sufficient facts to be considered reliable, as Wooldridge took no steps to verify or investigate that the claims in the patent were invented at the University.

The University has conceded that to the extent that Wooldridge proffers opinions that are essentially legal conclusions, these opinions will be withdrawn. Thus, to the extent that Wooldridge proffers legal conclusions regarding the University's ownership interest or the parties' rights and obligations under the Bayh-Dole Act or University policies, his opinions will be excluded. See Berry, 25 F.3d at 1353 (excluding expert's legal conclusion on grounds that testimony would

"invade[] the province of the court"). However, to the extent that the University seeks to offer Wooldridge as an expert, based on his experiential knowledge, to provide insight and general background regarding such matters as how a university would evaluate its potential interest in a patent or invention; what a university would look to in determining its interest (*i.e.*, the status of the inventor, the sponsorship of the research, and the obligations and rights of the respective entities involved under the Bayh-Dole Act); and what documents might be filed, such as election of title or invention disclosures, as well as general insight and background on the issues of licensing, assignments, releases and the like, the Court finds that the University has shown that Wooldridge has specialized knowledge and experience in the area of university technology transfers and that his opinions in this regard would be helpful to the trier of fact.

B. Value of Reasonable Royalty

Next, the defendants argue that Wooldridge is not qualified to opine as to the value of a reasonable royalty from a license in this case because he is not an economist and has failed to established how he is qualified to opine as to the value of a reasonable royalty for a medical imaging device, such as the PET/CT Scanner. Second, the defendants argue that Wooldridge's testimony in this regard is not reliable in that he applies no methodology in determining a reasonable royalty. Further, the defendants contend, evidence of the value of a reasonable royalty is not relevant in this case because the parties did not have a license agreement.

Upon reviewing Wooldridge's report and his testimony at the Daubert hearing, the Court is satisfied that Wooldridge is qualified to address the framework and factors considered by a university technology transfer office in valuing intellectual property. The Court further finds that Wooldridge's analysis, which culminates in the opinion that a royalty rate of "2% to 4% would be

within a reasonable range" if a license were obtained on a medical device such as the subject PET/CT scanner, is sufficiently reliable. In determining a range for a reasonable royalty, Wooldridge notes in his report that there are several basic approaches in valuing a university's interest in technology and establishing a royalty rate, including evaluating the cost incurred in creating or purchasing the technology; evaluating comparable rates, derived from industry standards, public documents, and case law; and determining the contribution of the technology to the overall operating profit of the device. With respect to evaluating comparables, Wooldridge cites a 2004 presentation from the president of RoyaltySource, which provides an average royalty rate in various industries, including medical/health products, as well as an "oft-quoted presentation at the 1989 AUTM Annual Meeting" from Lita Nelsen of the Massachusetts Institute of Technology, which provides a table of average royalty rates in various industries, including medical devices. Wooldridge further testified at the Daubert hearing that he relied on his experience with over 400 licenses and the related royalties generated by these agreements in arriving at a reasonable royalty range.

Moreover, the Court finds that Wooldridge's testimony on this issue is relevant; the University bases its damage claim, at least in part, on a theory that had the defendants disclosed material facts and Dr. Townsend not breached his employment obligations, the University would have been entitled to a license agreement that would have included compensation, including the payment of a reasonable royalty. As such, the fact that the parties may not have had an enforceable license agreement does not render this testimony irrelevant.

C. Standard Technology Transfer Practice

Next, the defendants argue that, to the extent that Wooldridge seeks to testify as to any industry standard for technology transfer procedure, he lacks the requisite qualifications to testify as to such a standard because he only has experience with Carnegie Mellon. Further, the defendants argue, Wooldridge fails to identify the standard on which he bases his conclusion and repeatedly admitted in his deposition that either there is no standard on particular issues or that he could not identify an applicable standard.

The Court cannot say that Wooldridge lacks the qualifications to testify as to the generally accepted standards or practices in technology transfer procedures. The defendants correctly point out that the majority of Wooldridge's experience with technology transfer practices has been through his work at Carnegie Mellon, and while the Court finds that this experience gives Wooldridge an adequate basis for his testimony on this issue, the Court also agrees with the defendants that the particular standards practiced at Carnegie Mellon (to the extent that they deviate from generally accepted standards used by universities in general) are not necessarily relevant to this matter. However, Wooldridge testified at the Daubert hearing that, in addition to his work at Carnegie Mellon, he is actively involved in the Licensing Executive Society and the Association of University Technology Managers. Wooldridge testified that through his work at Carnegie Mellon as well as these professional societies, he has worked with numerous other universities and has become generally familiar with other universities practices and procedures. Further, while Wooldridge admitted that no "accredited" standard applies to technology transfer, he did identify numerous guidelines, including those set forth by the AUTM, as being applicable to technology transfer issues. The Court is satisfied that Wooldridge has established a reliable basis for his

opinions regarding standard technology transfer practice. To the extent that he may not be familiar with any accredited standards or with all of the particular aspects of technology transfer standards, such unfamiliarity goes more to the weight to be afforded his testimony than its admissibility. See Barreto, 268 F.3d at 333. Further, while the defendants have established that there may be substantial fodder for cross-examination of this expert regarding the various specifics of this case, this might affect the trier of fact only in the weight to be given the witness's testimony. It does not undermine his qualification on this issue.

D. Interpretation of Bayh-Dole Act

Lastly, the defendants take issue with Wooldridge's opinions with the applicability of the Bayh-Dole Act and/or its impact on these particular parties' rights and obligations. For the reasons stated previously, the Court agrees with the defendants that Wooldridge's opinions on both of these issues are essentially legal conclusions and should be stricken. However, the Court finds that the University has established that Wooldridge is sufficiently qualified to testify as to the general customs and practices of university technology transfer offices under the Bayh-Dole Act. The Court finds this to be a complex issue, of which Wooldridge has specialized knowledge and experience, for which expert testimony could likely prove useful to a jury in explaining terminology, how the law impacts the relationships of universities subject to the Act (in terms of general rights and obligations), and the procedural issues arising therefrom. See United States v. Van Dyke, 14 F.3d 415, 422 (8th Cir. 1994) (finding trial court erred in precluding expert from testifying regarding her explanation of a detailed banking regulation); United States v. Leo, 941 F.2d 181, 196 (3d Cir. 1991) (allowing expert to testify regarding custom and practices of defense industry under Armed Services Procurement Act of 1947). However, Wooldridge is not qualified to testify as to whether

the Bayh-Dole Act is applicable in this case, nor can he testify as to how the Bayh-Dole Act applies in this particular case or how it impacts these parties' rights and obligations thereunder.

For the foregoing reasons, Defendants' Motion *in Limine* to Exclude the Testimony of Plaintiff's Proposed Expert Robert Wooldridge [Doc. 77] is **GRANTED IN PART** and **DENIED IN PART**.

II. Thomas Lewellen

The defendants move to exclude from trial any and all testimony of the plaintiff's proposed expert, Dr. Thomas Lewellen. [Doc. 79]. For grounds, the defendants argue that Dr. Lewellen is not qualified to proffer opinions on the six discrete issues identified in his expert report, and that he has not applied any reliable methodology or offered relevant testimony as to these issues. Additionally, the defendants contend that Dr. Lewellen took no independent steps to understand or investigate the constituent components of the commercial PET/CT scanner and provides no scientific or technical analysis of the device. Therefore, despite Dr. Lewellen's experience in the field of PET physics, the defendants argue that he should be excluded from testifying as to each of the six issues upon which the plaintiff has offered him as an expert.[2]

The University counters that Dr. Lewellen is well qualified in the field of PET/CT due to his unique and specialized personal experience with PET/CT scanners, and that he has properly applied his specialized expertise in reaching his opinions on this matter. The University

[2]In their motion, the defendants also move to exclude Dr. Lewellen's testimony on the grounds that he destroyed copies of his draft reports or copies of his e-mail correspondence with plaintiff's counsel. For the reasons already stated in this opinion, the Court will not exclude Dr. Lewellen's testimony on this basis.

further argues that Dr. Lewellen's opinions are relevant and reliable, and that they will assist the trier of fact. Accordingly, the University requests that the defendants' motion be denied.

A. Dr. Lewellen's Experience with PET/CT

While not challenging Dr. Lewellen's qualifications as a PET physicist, the defendants argue that Dr. Lewellen does not have sufficient experience and expertise concerning the CTI/CPS commercial PET/CT scanner to render opinions regarding whether certain concepts, intellectual property, methods or techniques related to the PET/CT scanner were developed at the University and used or applied in the CTI/CPS commercial PET/CT scanner. The defendants argue that Dr. Lewellen's only experience with a commercial PET/CT scanner is through his general experience in the industry, and that such limited and general experience does not qualify him to testify as to the operations, sub-components and software of the commercial PET/CT scanner.

The University counters that in addition to his expertise in PET physics, Dr. Lewellen has unique and specialized personal experience with PET/CT scanners. It is from this specialized knowledge, the University contends, that Dr. Lewellen is able to make comparisons between the University's records of the development efforts at the University and the characteristics of the current commercial PET/CT scanner.

Dr. Lewellen is a Professor of Radiology at the University of Washington with training and funded grants in various aspects of positron emission tomography ("PET"). [Doc. 79, Ex. A, Lewellen Report at 2]. Dr. Lewellen testified at the Daubert hearing that he has experience with PET/CT scanners, specifically, through "acceptance testing"[3] of two generations of the subject

[3]According to Dr. Lewellen, "acceptance testing" involving running the machine using a "phantom" patient and analyzing the resulting data for accuracy.

commercial PET/CT scanner, as well as several scanners manufactured by Siemens, Philips, and GE. Dr. Lewellen was also involved with the purchase, evaluation, and testing of a PET/CT scanner at the University of Washington.

While Dr. Lewellen worked toward his Ph.D., he was involved in building particle and gamma ray detection systems, which is a science similar to what is involved in PET/CT as both involve the detection of gamma rays.

Dr. Lewellen has experience with the University of Washington PET scanners, including the Pett Electronics SP-3000 time-of-flight PET system, which was developed at Washington University in St. Louis and was the first commercial time-of-flight PET scanner ever produced. Specifically, Dr. Lewellen and his group implemented their own data acquisition system and mated it to the scanner. After initial operations and some work, the group determined that the detector blocks had a design fault in the light reflector, so the group designed a new light reflector and rebuilt all of the detector modules. The group went on to work with Pett Electronics to develop a new discriminator design for the scanner, as well as to design and construct new electronics for the system.

Dr. Lewellen was also part of a "focus group"at the University of Washington that defined the requirements for the Advance PET Scanner for GE. Before it was released commercially, a version of the scanner was installed at the University of Washington, and Dr. Lewellen was part of the installation team. This team also did some of the initial testing, as well as maintenance and repair work, on the device.

Dr. Lewellen also worked on GE's DSTE scanner. He and his group were involved in the purchasing, installation, testing, and service of this device at the University of Washington.

Dr. Lewellen testified that he and his group are involved in the design and construction of small animal PET scanners. Specifically, the group developed the entire design process, including the selection of crystals and phototronics, the development of the detector modules, the design of the electronics integration of the system, and the development of the software tools.

Dr. Lewellen has also performed ACR certification testing on two PET scanners, which consists of scanning phantoms and training hospital staff on how to perform such testing on an annual basis.

With respect to the University of Washington's intellectual property, Dr. Lewellen testified that he has been involved with negotiation of patent and intellectual property clauses with the University of Washington's technology transfer department for grants and contracts with various companies. Additionally, he has submitted several invention disclosures to the University of Washington; has been listed on one patent application that has been submitted; has received royalty payments for a software license for a bone mineral scanning system; and has assisted in the development of test data for submittal to the FDA.

Dr. Lewellen further testified that he has had experience with federal grant funding and other grants, including preparing and submitting progress reports and other reports to the grant funding agency. He has also served as a peer reviewer for the National Institutes of Health ("NIH") and the Department of Energy ("DOE"). In this capacity, Dr. Lewellen has reviewed NIH grants for the development of PET, SPECT, PET/CT, and SPECT/CT scanner technologies. Finally, Dr. Lewellen testified that he and his group at the University of Washington have recently published two papers and two abstracts regarding PET/CT technology.

Upon review of the evidence of Dr. Lewellen's background and experience, the Court is satisfied that Dr. Lewellen has adequate specialized knowledge to proffer opinions regarding the subject PET/CT scanner. While Dr. Lewellen admittedly has more experience in the field of PET physics, it is not required that a proffered expert have specific expertise in the specialized area at issue. Where a witness is qualified in a general relevant field, the witness's lack of familiarity with specific aspects of the specialized field at issue merely goes to the weight and credibility of the testimony, not its admissibility. See Surles, 474 F.3d at 295 (finding expert with knowledge of general threat assessment was qualified despite lack of expertise in the "very specialized area of commercial bus line threat assessment"); Barreto, 268 F.3d at 333 (noting plaintiff's "unduly narrow approach to defining the central issue at trial" and unfamiliarity with certain aspects of the issue at hand "merely affected the weight and credibility of [the expert's] testimony, not its admissibility"). Accordingly, the Court will not exclude Dr. Lewellen's opinions on this basis.

B. Dr. Lewellen's Opinions

Dr. Lewellen opines in his report as follows:

> [T]he NIH funded work at the University of Pittsburgh did have an impact on the development of the commercial PET/CT scanner technology by CPS/CTI and that Dr. Townsend, working as faculty of the University of Pittsburgh, as well as other University of Pittsburgh employees, including but not limited to Dr. Paul Kinahan, Thomas Beyer and Dr. Carolyn Meltzer, made major contributions to the invention and reduction to practice of the PET/CT scanners developed by CPS/CTI.

[Id. at 13].

In reaching this conclusion, Dr. Lewellen initially reviewed a series of documents relative to this lawsuit, including grant progress and financial reports, copies of patents, software

code, depositions of several individuals, correspondence between several individuals, and several internal documents from CTI/CPS concerning the development of a PET/CT product by that company. Dr. Lewellen expressed an initial opinion "that a portion of the background knowledge, data sets, and general expertise in PET/CT utilized by CTI/CPS in deciding to develop a PET/CT scanner, submitting patents, and eventual development of a production system are derived from work done at and by employees of the University of Pittsburgh." [Id.]. Subsequently, legal counsel for the University posed six questions for Dr. Lewellen's consideration, to which Dr. Lewellen responded in his report. The defendants challenge Dr. Lewellen's ability to testify as to each of these six issues. The Court will address each issue in turn.

1. Whether the commercial PET/CT scanner derived from work at the University

In response to question one, Dr. Lewellen opines that Dr. Townsend's work at the University of Pittsburgh contributed to the development process of the commercial scanner and that his work at the University was utilized in the subsequent patents. Additionally, Dr. Lewellen opines that the NIH funded work at the University contributed to both the prototype and commercial scanner development.

In reaching this conclusion, Dr. Lewellen relies upon his review of the NIH grant documentation. Specifically, Dr. Lewellen notes (1) statements in the NIH grants referring to the "collaborative effort" between the University and CPS; (2) a reference in the NIH grant to the fact that CPS did not have sufficient funds to develop a prototype system and that NIH grant funds were needed to procure the necessary components; (3) the presence of standard NIH intellectual property clauses concerning the ownership of inventions and other intellectual property matters and the lack of any statements by CPS in the grants that CPS would not agree to the standard intellectual property

arrangements; (4) a reference in the NIH final report to the involvement of Thomas Beyer (a Ph.D. student paid on the NIH grant) in "all aspects of the design, performance evaluation, installation and operation within the UPMC PET facility"; and (5) a reference in the NIH final report to Dr. Kinahan and others developing algorithms for use in the prototype scanner. While Dr. Lewellen notes that the NIH final report "does not provide enough detail to clearly defined [sic] what parts of the design effort were based on or performed by efforts at the University of Pittsburgh," he notes that the report nevertheless "clearly indicate[s] th[at] there were significant contributions to the definition and reduction to practice of the PET/CT scanner by University of Pittsburgh personnel." [Lewellen Report at 4-5].

In addition to the NIH report, Dr. Lewellen cites several other documents, including academic papers, CPS/CTI reports, letters from Siemens, and an article in Time magazine, which all reference the support from the NIH grants in the development of the commercial PET/CT scanner. [Id. at 5].

In opining that Dr. Townsend specifically was active in the development of the PET/CT scanner while at CPS, and that in so doing, he was acting as an agent of the University, Dr. Lewellen cites to letters from the University outlining the conditions for Dr. Townsend to remain as a faculty member while working at CPS part-time; CPS internal emails and memoranda indicating that Townsend's role while at CPS was one of supervision and technical input in the PET/CT scanner; the NIH final report, which references Dr. Townsend's work with CPS; and Dr. Townsend's inclusion in the submitted patent applications. [Id. at 6-7].

Finally, in opining that the design decisions for the commercial product were influenced by the experience at the University, Dr. Lewellen cites internal CPS documents referring

to the University prototype, as well as the inclusion of data sets from the University in the patent applications and the inclusion of the prototype design as one of the system designs claimed in the patents. [Id. at 7-8].

The defendants argue that Dr. Lewellen should not be permitted to testify about whether the PET/CT scanner marketed and sold by CTI/CPS derived from the work at the University because he did not independently review the work done at the University; he did not review or investigate the commercial PET/CT scanner; he did not apply any scientific method in his analysis; and his analysis is based on incorrect factual assumptions. The defendants further argue that because Dr. Lewellen's analysis consists of merely reviewing documents, his testimony will not assist the trier of fact.

The University counters that Dr. Lewellen's review of deposition testimony and documents produced in discovery in forming his opinions was appropriate in this case. Specifically, the University argues that an expert with specialized knowledge, such as Dr. Lewellen, can rely on his expertise and review of documents to arrive at opinions, citing McCullock v. H.B. Fuller Co., 61 F.3d 1038 (2d Cir. 1995), Carroll v. Morgan, 17 F.3d 787 (5th Cir. 1994), and Smith v. Ingersoll-Rand Co., 214 F.3d 1235 (10th Cir. 2000). Moreover, the University argues that Dr. Lewellen did not have to review the technical specifications or the software utilized in the commercial scanner in order to opine regarding the University's contributions of know-how. With respect to the alleged factual inaccuracies relied upon, the University argues that these are not "fundamental foundations or assumptions" and therefore do not render Dr. Lewellen's overall opinions unreliable. Finally, the University argues that Dr. Lewellen's opinions will assist the trier of fact because his specialized experience enables him to identify how the development record reflects know-how contributions of

the University of Pittsburgh and how such know-how contributed to the commercial PET/CT scanner.

The Court shares the defendants' concerns regarding the reliability and relevancy of Dr. Lewellen's opinions, and particularly the ability of his testimony to assist the trier of fact in this case. In this first question, Dr. Lewellen was asked whether the commercial PET/CT scanner "derive[d] from" any "work efforts" of University employees, and specifically, whether Dr. Townsend and other University employees contributed to the commercial scanner invention and whether Dr. Townsend and other University employees developed know-how which contributed to the commercial scanner. In responding to these inquiries, Dr. Lewellen did not review the actual "work efforts" at the University, nor did he examine the technical specifications, software, or components of the commercial scanner in order to compare them to what specifications, software, or components were developed by the University. Further, he did not utilize his specialized knowledge of PET and PET/CT physics to explain what know-how was actually developed at the University and in what manner this know-how actually contributed or otherwise influenced the ultimate commercial product. Rather, Dr. Lewellen reviewed the NIH grant materials and other documents produced in discovery and provided a synopsis of this documentary evidence. Based on these documents, Dr. Lewellen's report provides a factual narration of his understanding of Dr. Townsend's history with the University of Pittsburgh and his role as a consultant with CPS and summarizes how these documents constitute evidence of the University's contributions to the development of a commercial scanner. However, as he admits in his report, the NIH final report "does not provide enough detail to clearly defined [sic] what parts of the design effort were based on or performed by efforts at the University of Pittsburgh."

The Court's concern with these materials serving as a basis for Dr. Lewellen's opinions is two-fold. First, there has been no showing that the approach taken by Dr. Lewellen in relying upon the NIH report, various e-mails, letters, and articles, is a reliable basis for forming opinions regarding the University's actual contributions to this product. There has been no showing that, in relying upon these documents, Dr. Lewellen has "employ[ed] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire, 526 U.S. at 152.

Second, and more importantly, there has been no showing that Dr. Lewellen's specialized knowledge of PET and PET/CT physics would assist the trier of fact in understanding these documents. Most of the documentary evidence reviewed and relied upon by Dr. Lewellen does not even appear to scientific in nature, and the Court fails to see how Dr. Lewellen's specialized knowledge informs his interpretation of these documents. For example, Dr. Lewellen states in his report that the NIH grant "clearly state[s] (both in the main grant narrative and in the supporting letters from CPS), that the development of the PET/CT prototype system was a collaborative effort between the University of Pittsburgh and CPS," and that the NIH grant further states that the CPS development group did not sufficient funds available to develop such a system and that NIH funds would be necessary to procure components. From these statements, Dr. Lewellen surmises that "the NIH Grant was part of the resources utilized by CPS and Dr. Townsend for the prototype system development." [Lewellen Report at 4]. The Court fails to see how Dr. Lewellen's specialized knowledge informs this conclusion, nor does the Court see how Dr. Lewellen's specialized knowledge renders his interpretation of these documents any more persuasive than a lay person's interpretation.

The documents relied upon by Dr. Lewellen can be admitted as evidence, and the attorneys can argue as to the proper conclusions to be drawn from them; the jury can draw their own inferences, make their own interpretation of the language, and reach their own conclusions, without the assistance of expert testimony. See, e.g., Hoffman v. Caterpillar, Inc., 368 F.3d 709, 714 (7th Cir. 2004) (in ADA case, finding expert testimony based on review of videotape would not assist the trier of fact because videotape could be played for jury and jury could draw its own inferences regarding the plaintiff's ability to meet production levels); Taylor v. Ill. Cent. R.R. Co., 8 F.3d 584, 585-86 (7th Cir. 1993) ("This issue, already before the jury in several instances, boils down to whether a pile of large rocks is harder to stand on than a pile of smaller rocks. Notwithstanding [the expert's] lengthy experience in the railway industry, any lay juror could understand this issue without the assistance of expert testimony."); SEC v. Lipson, 46 F. Supp. 2d 758, 763 (N.D. Ill. 1998) ("Expert testimony may not be used merely to repeat or summarize what the jury independently has the ability to understand.").

While the University argues that Dr. Lewellen's document review was proper, the cases it relies upon are clearly distinguishable from the present case. For example, in McCullock, the plaintiff's expert, who was an experienced medical doctor who practiced in the specialty of ears, nose, and throat, reviewed the plaintiff's medical records and opined on the causes of the plaintiff' throat ailment, thus utilizing and applying his medical expertise to render a medical opinion. 61 F.3d at 1043. In Carroll, the challenged expert was a cardiologist with thirty years of experience, who reviewed the decedent's medical records in order to determine the cause of death, thus utilizing and applying his medical expertise to render a medical opinion. 17 F.3d at 790. Notably, in neither of these cases did the defendants challenge the propriety of these medical experts reviewing medical

records as a basis for their opinions. Nor would such a challenge be anticipated, as it is common for medical doctors to base their expert medical opinions upon review of a patient's written medical history. However, in the present case, there is nothing in the record to indicate that the type of document review performed by Dr. Lewellen is commonly undertaken by scientists in his field in order to determine whether certain scientific research and work contributed to the development of a particular device. Furthermore, the opinions expressed by the experts in the cited cases required the application of specialized medical knowledge to particular facts and data, *i.e.*, the documentation of symptoms in the medical records, in order to render a medical opinion on the cause of a medical condition. As explained above, Dr. Lewellen did not apply any specialized knowledge or his proffered expertise in interpreting the documentation in the present case.

In Smith, the third case cited by the University, the plaintiff's experts testified that, based upon their review of depositions and other discovery material, the defendant failed to conduct adequate analyses and risk assessments before marketing the milling machine that injured the plaintiff. Id. at 1243-44. The defendant argued that both experts' opinions were unreliable because neither had firsthand knowledge with milling machines. Id. at 1244. The Tenth Circuit disagreed, noting that experts are not required to have firsthand knowledge of the machine at issue in order for their testimony to be admissible. Id. Indeed, the Court noted that the experts' testimony "focused on the procedures [the defendant] followed in developing and marketing the milling machine, an area into which firsthand observation of the machine would shed little light." Id.

The Court also finds Smith distinguishable from the present case, as it appears that these experts were applying their specialized knowledge and expertise in evaluating the safety measures and testing performed by the defendant before the milling machine was marketed. Dr.

Lewellen, on the other hand, is not applying his specialized knowledge or expertise in evaluating the NIH grant and other documents discussed in his report. Rather, his "opinion" appears to be more of a lay opinion, summarizing the contents of certain documents which allegedly reflect the University's contribution to the commercial product. Such opinions do not appear to require, or even utilize, his specialized knowledge or expertise in PET physics or experience with PET/CT scanners.

The Court finds the case of Fisher v. Ciba Specialty Chemicals Corp., 238 F.R.D. 273 (S.D. Ala. 2006) to be particularly instructive. In that case, the plaintiff property owners brought a putative class action against the defendant chemical company, alleging that they had incurred damages due to the company's pesticide manufacturing. The defendants sought to strike or exclude the expert reports submitted in favor of the plaintiff's motion for class certification. The plaintiff's pharmacology and toxicology expert, Dr. Farber, submitted a report which provided the Court with a detailed discussion on the history and properties of DDT. The Court refused to exclude Dr. Farber, noting that his report "reveal[ed] information that the Court has found nowhere else in the voluminous class certification record," and while noting that such information was not crucial to the Court's class certification analysis, "it is unquestionably useful background data that has enhanced and enriched the undersigned's understanding of the primary chemical compound of interest in this lawsuit." Id. at 280.

The Fisher Court, however, excluded the plaintiff's administrative law expert, Ms. McFaddin. In so doing, the Court noted as follows:

> Much of her report appears to be a factual narrative of contamination-related events occurring at the Ciba plant, as well as Ciba's interactions with regulatory agencies, during the time period at issue. To the extent that McFaddin's report offers a synopsis of facts

> concerning the Ciba plant based on her reading of other exhibits, it does not state expert opinions at all, but simply provides the witness's slant on facts that are in the . . . record.
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> * * *
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> . . . The document reads like the fact section of a brief, not the report of an expert witness. The vast majority of McFaddin's report simply summarizes and states her advocacy-based interpretation of documents in the record concerning Ciba's historical conduct. These statements of alleged fact do not appear to benefit from, or to be based to any extent on, McFaddin's status as a regulatory expert. The Court's task in examining the Rule 23 issues presented here is not assisted by McFaddin's one-sided recitation of the record facts. She does not show that she has special skills that render her reading of record documents concerning the history of the Ciba plant, and her conclusions as to what Ciba has or has not done, any more or less persuasive than that of a layperson. For example, McFaddin concludes that Ciba has failed and refused to take action to remediate its off-site contamination. But how is that conclusion bolstered by her expertise as a "regulatory expert"? Is she not simply acting as another advocate for plaintiffs in arguing the facts in a manner that is most beneficial to her clients? How does this purported expert report differ from a supplemental brief submitted by another lawyer for plaintiffs?

Id. at 281.

Similarly, in the present case, instead of offering opinions based upon his specialized knowledge and expertise, Dr. Lewellen has offered his interpretation of facts that are already in the record. He has essentially marshaled the facts in the record which support the University's position. The Court finds that Dr. Lewellen's proffered opinions simply do not relate to, or benefit from, his expertise as a physicist. The Court does not find that Dr. Lewellen's opinions would therefore be helpful to the trier of fact on this issue. For these reasons, Dr Lewellen's opinions with respect to question one are excluded.

2. Whether the commercial PET/CT scanner derives from the NIH grants at issue

The second question posed to Dr. Lewellen was whether the commercial PET/CT scanner derived from the work done under the NIH grants at issue, that is, those for which Dr. Townsend was the primary investigator. Based upon his review of the documents (as described above) provided by the University's counsel, Dr. Lewellen concludes that "the commercial scanner design was influenced by the development of the prototype scanner with NIH funding." Dr. Lewellen bases this conclusion on several documents, including: (1) the two issued patents, which include figures identical to those in the NIH final report; (2) CPS documents which refer to the technical problems with the prototype scanner; (3) CPS documents which refer to the commercial scanner as a "second generation" scanner, thereby implying that the University's prototype scanner was the first generation system; and (4) the support letter from CPS in the NIH grant application which states that funding is needed for the prototype production to proceed. [Lewellen Report at 8].

Like his response to the first question, Dr. Lewellen's response to the second question involves pointing out documentary evidence in support of the University's claims and not the application of any specialized knowledge to facts or data. Moreover, Dr. Lewellen admitted in his deposition that he did not review the financial reports generated at the University detailing the allocation of funds under the NIH grants [Lewellen Dep. at 135]; the Court fails to see how Dr. Lewellen can testify as to what work was developed with grant funds without determining how the funds were actually spent. Accordingly, the Court does not find that Dr. Lewellen's opinion in this regard is reliable, nor would it be helpful to the trier of fact.

3. Whether the issued patents and pending patent application relate to the prototype and commercial PET/CT scanners

The third question that was posed to Dr. Lewellen asked him to describe how the two issued patents and the pending patent application relate to the prototype and commercial PET/CT scanner. More specifically, Dr. Lewellen was asked (1) whether the pending application encompasses the commercial scanner, and (2) in what ways the issued patents are distinct from the commercial scanner.

In his report, Dr. Lewellen begins his response to question three by noting that several publications and reports, which were submitted in support of the provisional patent application, make references to NIH support from grants, as well as contributions from University of Pittsburgh faculty and employees. He goes on state that the '476 patent contains "many items . . . that directly relate to the publications and reports associated with Dr. Townsend's NIH grants," including one of the three figures of possible geometries for the PET/CT scanner, which depicts the SMART scanner used in the prototype scanner, as well as several figures which are identical to those used in the NIH final report. Dr. Lewellen notes that the description in the '476 patent covers the SMART scanner, and that "[s]pot checking some of the language in the patent revealed sections that are word for word identical to sections from the NIH final report." Dr. Lewellen also discusses the various claims and notes that, based upon his reading of the claims, the '476 patent allows any mixture of the claims to be used for a PET/CT scanner. Dr. Lewellen also reviewed the '284 patent and notes in his report that the most significant change from the '476 patent was the moving of the SMART scanner geometry description into the claims section. [Lewellen Report at 9].

Finally, Dr. Lewellen reviewed the February 12, 2004 patent publication, which claims priority to the '476 and '284 patents. Dr. Lewellen notes that the 2004 publication has a greatly expanded claims section that essentially covers all of the variants for PET/CT scanners introduced in commercial products, and that it still includes the SMART scanner description as well as other descriptions that are identical to the NIH final report. Based upon his review of these documents, Dr. Lewellen concludes that "all of the patents and/or applications encompass the basic geometry and data processing schemes for both the prototype and current commercial scanners and demonstrate the impact of the NIH funding at the University of Pittsburgh on the development of PET/CT." [Id. at 10].

At the Daubert hearing, Dr. Lewellen testified that in reaching his opinions, he read the patent claims and compared them to the published work, namely the NIH final report, as he would do in conducting a peer review. He based his opinion regarding whether the patent claims are encompassed in the commercial scanners upon his familiarity and experience with the commercial PET/CT scanners, which he developed through his work in acceptance testing, observing commercial scanners with the covers removed at the CPS factory and on-site at a hospital during repairs, as well as his general conversations with Siemens and CPS representatives regarding the machines.

The defendants argue that Dr. Lewellen should be precluded from testifying as to how the two issued patents and the pending application relate to the prototype and commercial PET/CT scanners because Dr. Lewellen lacks the requisite training or skill to testify regarding these matters. They further argue that Dr. Lewellen simply compared the similarity in the wording between the NIH final report and the patents without applying any scientific method or analysis in his review.

The defendants also take issue with the fact that Dr. Lewellen did not investigate or analyze the commercial scanner in order to arrive at his opinions. Finally, the defendants argue that testimony as to the pending patent application is irrelevant, as the Court does not have jurisdiction to determine ownership of pending patents.

The University argues, on the other hand, that Dr. Lewellen's unique and specialized experience with PET/CT qualifies him to render an opinion regarding his review and comparison of these patents. Further, the University argues, because claims analysis is based upon "reading" the claims, there is no specific science or scientific methodology employed in such analysis. Finally, with respect to the defendants' argument that the Court lacks jurisdiction to determine the ownership of the pending patent, the University argues that this argument applies only to ownership issues derived from state law claims relating to assignment obligations and not to federal issues arising from inventorship.

The Court is satisfied that Dr. Lewellen has established his familiarity and general knowledge of how commercial PET/CT scanners operate. While admittedly part of Dr. Lewellen's analysis appears to involve non-expert commentaries (*e.g.*, the similarities in language utilized in various reports and patents), it does appear that he utilized his specialized knowledge and training to compare the basic geometries, data processing schemes, and variants for PET/CT scanners in his comparisons. The Court finds that Dr. Lewellen's specialized knowledge of these machines enables him to testify regarding how the patent claims relate to both the prototype scanner and to the commercial scanner with respect to these particular aspects of the invention. The fact that Dr. Lewellen did not physically inspect a commercial scanner in detail for the purpose of forming his opinions in this case is an issue that goes to the weight of Dr. Lewellen's opinion, not its

admissibility. Finally, with respect to the defendant's jurisdictional arguments, the Court notes that Dr. Lewellen does not purport to give an opinion on the subject of ownership. [Lewellen Dep at 150]. In any event, the defendants' argument regarding jurisdiction is the subject of a pending motion for summary judgment; accordingly, the Court will defer to the District Court to determine this issue.

4. Whether the FDA approval process benefitted from the prototype scanner test data

In question four, Dr. Lewellen was asked whether the test data obtained from the prototype scanner benefitted the FDA approval process for the commercial scanner. Upon examining the documents submitted in support of the FDA application, Dr. Lewellen concludes as follows:

> [W]hile the scanner presented for the FDA application used different components from the prototype system, the application appears to have used at least one patient data set from the prototype scanner, refereed [sic] to the prototype scanner and included the primary descriptive paper of the prototype. Thus, the data from the prototype scanner did benefit the FDA application in at least a small way.

[Lewellen Report at 10].

The defendants argue that Dr. Lewellen should be precluded from testifying as to the use or benefit of test data generated from the prototype in the FDA approval process because Dr. Lewellen has never participated in the FDA application process and therefore is not qualified to testify as to whether certain items contained within an FDA application are beneficial to that process.

The University counters that Dr. Lewellen's opinions on test data are reliable and relevant. Specifically, it argues that Dr. Lewellen can assist the factfinder by explaining (1) what

patient test data is; (2) how patient test data is obtained from the scanner; and (3) how patient test data improved upon prior technology. While the Court agrees that Dr. Lewellen may be helpful in providing background and explaining such terminology to the jury, that is not what Dr. Lewellen purports to do in his expert report, nor is his qualification to proffer such explanations an issue that is before this Court. Rather, he attempts to opine on the impact of the prototype scanner patient test data on the FDA approval process. In his deposition, he admitted that he is not sufficiently knowledgeable regarding the FDA approval process to opine whether this test data impacted the process, but could testify only that the data was part of the package that was submitted. [Lewellen Dep. at 168]. The Court finds that Dr. Lewellen is not qualified to render an opinion regarding the impact of the patient test data on the FDA approval process, and further the Court finds that Dr. Lewellen's speculation regarding the impact of patient test data on the FDA approval process would not be necessary or helpful in explaining to the jury what documents were submitted to the FDA. Accordingly, Dr. Lewellen's opinions with respect to question four will be excluded.

5. Paul Kinahan's contributions to the 2004 patent publication

In question five, Dr. Lewellen was asked about the contributions of Paul Kinahan to the claims of the 2004 patent publication. In his report, Dr. Lewellen opines that the attenuation correction used in the PET/CT scanners and claimed in the patents is based on the work of Dr. Kinahan and is essentially identical to the approach described in Dr. Kinahan's October, 1998 article. The defendants contend that Dr. Lewellen's opinions concerning the so-called Kinahan algorithms are so patently flawed that they are inherently unreliable under Daubert. Specifically, the defendants argue that Dr. Lewellen did not review the actual code of the commercial scanners to determine if the algorithms are in fact used. They further argue that Dr.

Lewellen improperly attributes the algorithm solely to Dr. Kinahan, when there were three other authors – Dr. Townsend, Thomas Beyer, and Donald Sashin – on the article. Further, the defendants argue that, in opining that the attenuation correction method was developed in 1998, Dr. Lewellen ignores and improperly tries to distinguish the 1994 conference publication by Thomas Beyer, along with Kinahan, Townsend, and Sashin, which describes an attenuation correction method.

The University counters that Dr. Lewellen's opinions are relevant and reliable. Specifically, it argues that the attenuation correction methodology stands apart from the software code, and that the defendants have acknowledged that the methodology remains in use in the commercial scanners. With respect to evidence that the method was actually developed in 1994, the University cites Dr. Townsend's NIH Final Report, which indicates that the attenuation correction process was not completed in 1994.

The Court is satisfied that Dr. Lewellen's specialized knowledge and familiarity with PET/CT scanners and the aspects of attenuation correction, attenuation correction algorithms, and their use in PET/CT scanners, enables him to render an opinion regarding the contributions in these areas of Paul Kinahan and the other authors of the 1998 article to the 2004 patent publication. While Dr. Lewellen did not review the actual software code utilized in the commercial scanner, he explained at the Daubert hearing that such review was not necessary as he was only opining that the general concept and/or approach of the hybrid method for CT-based attenuation correction developed in the 1998 Kinahan paper was being used. He further clarified his report by explaining that he was not trying to suggest that Dr. Kinahan developed the algorithms on his own, and that it would be more precise in referring to the work by Dr. Kinahan to refer to all four contributors to the 1998 article. Further, the Court finds that Dr. Lewellen's attempts to distinguish the 1994 Beyer

paper do not render his opinions on this issue unreliable. Such issue goes more to the weight to be afforded to Dr. Lewellen's opinion rather than its admissibility, and the defendants are free to cross-examine Dr. Lewellen regarding the 1994 paper.

6. Dr. Meltzer's role in the development of know-how and/or patient data

The sixth question posed to Dr. Lewellen asked him to describe the role that Dr. Meltzer played in the development of any know-how and/or patient data while employed by the University. Dr. Lewellen begins by noting that Dr. Meltzer served as the medical director of the PET facility at the University of Pittsburgh until 2002; that she assisted in testing of the commercial scanner in 2000-2001; and that she "was an integral part of developing the scanning protocols for the commercial scanner and therefore contributed to know-how, which should be owned by the University." Citing the deposition of Charles Watson, an email from Watson suggesting what Dr. Meltzer and Dr. Townsend should discuss at a PET/CT Users Meeting regarding their clinical experience at the University, a PET/CT Users Meeting Agenda showing Dr. Meltzer as a featured speaker, and a paper written by Dr. Meltzer entitled "Initial Experience with a CTI PET Systems PET/CT scanner at the University of Pittsburgh," Dr. Lewellen concludes that "[i]n view of Dr. Meltzer's contributions to the protocol for the commercial scanner the University of Pittsburgh, through her employment relationship, has an ownership interest in the know-how developed." [Lewellen Report at 11-12].

The defendants argue that Dr. Lewellen should be excluded from testifying as to the role Dr. Meltzer played in the development of any know-how and/or patient data while employed at the University. Specifically, they argue that Dr. Meltzer's role is not the proper subject of any

expert testimony, but rather is a factual question that can be answered by the individuals involved in the PET/CT development itself.

The University contends that Dr. Lewellen's knowledge and experience can assist the jury in understanding the work of Dr. Meltzer and its relationship to the development process.

The Court agrees that ascertaining the role that Dr. Meltzer played in the development of know-how and/or patient data is purely a factual issue and is not the appropriate subject of any expert testimony. Like Dr. Lewellen's opinions with respect to questions one and two, Dr. Lewellen's opinions with respect to question six involves primarily the marshaling of facts from various documents. The Court fails to see how Dr. Lewellen's specialized knowledge informs this conclusion, nor does the Court see how Dr. Lewellen's specialized knowledge renders his interpretation of these documents any more persuasive than a lay person's interpretation or would be helpful in assisting the jury in making this factual determination. Accordingly, Dr. Lewellen will not be permitted to testify on this issue. Further, the Court finds that Dr. Lewellen's opinion regarding the ownership interest gained by the University through Dr. Meltzer's work is simply a legal opinion, unsupported by any scientific analysis or methodology, and thus should be excluded as well. See Woods v. Lecureux, 110 F.3d 1215, 1221 (6th Cir. 1997) ("[t]estimony . . ., which attempts to tell the jury what result to reach and which runs the risk of interfering with a district court's jury instructions, hardly can be viewed as being helpful to the jury").

7. Legal Conclusions and Arguments

Finally, the defendants argue that throughout his report, Dr. Lewellen attempts to offer opinions that amount to impermissible legal conclusions regarding the impact of the Bayh-Dole Act, the effect of agreements between Dr. Townsend and the University, the existence of an agency

relationship between Dr. Townsend and the University, and the effect of Dr. Meltzer's work on the University's ownership interest in the know-how developed. The University counters that these comments do not detract from Dr. Lewellen's technical expertise and related opinions.

The Court agrees that the cited examples from Dr. Lewellen's report are nothing more than impermissible legal conclusions, and Dr. Lewellen shall be precluded from offering such opinions at trial.

C. Conclusion

In summary, the Court finds that Dr. Lewellen is qualified, based upon his specialized knowledge and expertise, to render opinions regarding how the two issued patents and pending patent application relate to the prototype and commercial PET/CT scanners (question three) and regarding the contributions of the Kinahan algorithm to attenuation correction and to the claims of the 2004 patent publication (question five). To the extent that Dr. Lewellen seeks to proffer opinions regarding any other of the questions posed in his report, the Court finds that these are issues that do not require the admission of expert testimony in order to assist the trier of fact. Further, Dr. Lewellen shall be precluded from testifying as to any legal opinions or legal conclusions stated in his report. For the foregoing reasons, Defendants' Motion in Limine to Exclude the Testimony of Plaintiff's Proposed Expert Thomas Lewellen [Doc. 79] is **GRANTED IN PART** and **DENIED IN PART**.

III. Mark Gleason

Finally, the defendants seek to exclude the testimony of Mark Gleason, the University's damages expert. Gleason is a certified public accountant and managing director of Gleason & Associates, P.C., a firm that provides a variety of accounting, tax, and consulting services with an emphasis in the areas of financial reorganizations, business valuations, and litigation support. [Ex. 2, Gleason Report App. 2].

In preparing his report, Gleason met with counsel to understand the background of this litigation; read various documents produced through discovery; met with Marc Malandro, the University's Director of the Office of Technology Management to discuss the background of this case and the University's licensing policies; performed independent research using publicly available information; identified CTI's sales of the combined PET/CT scanner; and determined a reasonably royalty rate due to the University. [Gleason Report at 6].

In his report, Gleason states as follows:

> We have determined that the University's compensatory damages for CTI's wrongful use of the Combined PET/CT Scanner Intellectual Property are best measured by estimating the license fee that the University should have received from the Defendants for use of the Combined PET/CT Scanner Intellectual Property. Given the University's inability to commercially exploit technology developed by their faculty, staff, and students and their policy to regularly license such technology, the University would have realized value from the Combined PET/CT Scanner Intellectual Property through a license agreement. Thus, the potential damages experienced by the University due to the alleged actions of the Defendants are a loss of the royalty or license payments it would have received for use of the Combined PET/CT Scanner Intellectual Property from CTI, or others such as General Electric.

[Id. at 6-7 (footnote omitted)]. Gleason further notes that his opinions are based upon the following assumptions: (1) that the hypothetical negotiation between the University and CTI would have taken

place in October, 2001, when CTI sold the first commercial PET/CT scanner; (2) that the University had a co-ownership interest with CTI in the '476 and '284 Patents, the 2004 Patent Publication, and the scanner process; and (3) that the University had a full ownership interest in the know-how, copyrights, and patient test data. [Id. at 7].

In determining a reasonable royalty rate, Gleason applied the fifteen factors set forth in Georgia-Pacific Corp. v. United States Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), modified and aff'd, 446 F.2d 295 (2d Cir. 1971). While noting that these factors were originally developed to determine damages in a patent infringement case, Gleason states that the factors are useful in estimating a reasonable royalty rate in the present case. [Id.]. As part of his analysis, Gleason requested that the University provide him with historic licenses negotiated by the University in connection with the following subject areas: (1) medical device technology; (2) medical scanning technology; (3) test data; and (4) co-ownership. The 34 licenses provided by the University span dates from 1997 to 2006. [Id.]. Additionally, Gleason conducted other research and reviewed third party sources as to applicable license rates. [Doc. 89, Ex. C, Gleason Declaration at ¶2].

Based upon his analysis, Gleason opines that a reasonable royalty rate for the University's ownership interest in the Combined PET/CT Scanner Intellectual Property would be 2% of the net sales of any CTI Combined PET/CT Scanner. He calculates the total financial damages, based upon this 2% royalty rate, to be approximately $12.6 million, not including pre-judgment interest. [Gleason Report at 23]. In a supplemental report dated August 22, 2006 [Ex. 2 Tab B], Gleason revises this figure, based upon the inadvertent inclusion of CTI's ART scanners (which are not combined PET/CT scanners) when determining the total amount of sales from

combined PET/CT scanners that would be subject to a royalty to the University. Accordingly, Gleason reduced the overall damage calculation to $12,577,846. [Id. at 2].

In moving to exclude Gleason's testimony, the defendants first argue that Gleason's reasonable royalty rate theory does not "fit" the facts of this case because there is no license agreement and there is no allegation of patent infringement. Further, the defendants point out, CTI is a co-owner of the patented technology and thus would not have needed to license the technology from the University. The defendants contend that the University has not shown any authority to support the use of the Georgia Pacific factors to estimate a reasonable royalty between the co-owners of patents. [Doc. 81].

The University counters that the use of a reasonable royalty rate is appropriate in this case, even if there is no underlying patent infringement claim. The University cites three cases, Avery Dennison Corp. v. Four Pillars Enterprises Co., 45 Fed. Appx. 479 (6th Cir. Sep. 3, 2002); Ventura v. Titan Sports, Inc., 65 F.3d 725 (8th Cir. 1995); and University Computing Co. v. Lykes-Youngstown Corp., 504 F.2d 518, 537 (5th Cir. 1974), in which a reasonable royalty rate was used for the measure of damages absent any patent infringement.

Rule 702 of the Federal Rules of Evidence requires that expert testimony not only be reliable, but that it also assist the trier of fact. Fed. R. Evid. 702. "This requirement means that the proffered expert must "'fit' the facts of the case." Pride v. BIC Corp., 218 F.3d 566, 578 (6th Cir. 2000). Upon reviewing Gleason's report and supplemental report, the Court is satisfied that Gleason's use of the Georgia-Pacific factors and the assessment of a reasonable royalty rate "fit" within the facts of this case, despite the absence of an actual license agreement or claim of patent infringement. The University's claims against the defendants focus on the value of the intellectual

property that the University alleges it provided to the defendants with the expectation of receiving reasonable compensation in return. Under the University's theory, the value of this intellectual property and the compensation to be paid for the providing of the same can best be expressed by a license – in part, the University contends, because the Bayh-Dole Act prohibits the sale or assignment of intellectual property developed with federal grant funds. Based upon this theory, the Court finds that the "reasonable royalty" approach fits the University's claims, and that the Georgia-Pacific factors are a reasonable and reliable way to assess such a royalty.

Next, the defendants argue that Gleason's methodology of "bundling" the claimed intellectual property rights together is unreliable, and that there is no evidence that this method has been tested or reviewed or has any basis in the field of accountancy. The problem, the defendants contend, is that Gleason cannot "take apart" the bundle, and thus, his calculation becomes meaningless if a particular component was not used by the defendant, the University did not actually own a part of the bundle, or if some portion of the bundle in fact did not exist. The defendants go on to challenge several of Gleason's factual assumptions, arguing that CTI and CPS never used the patents at issue in the scanner; that the attenuation correction algorithms, which are included in the "know-how" part of the bundle, were already published and thus freely available to anyone without a need to license it from the University; and that the University had already been compensated for patient test data.

The Court finds that Gleason's methodology of "bundling" is reasonably reliable. As Gleason notes in his supplemental report, he has been informed by the University that it typically bundles intellectual property in a license. Further, as the University notes, CPS in its own Royalty Agreement with Dr. Townsend based Dr. Townsend's royalty on a combination of a patent

assignment and general undefined research and development or know-how contributions. The Agreement does not identify the value of the separate components of this "bundle." To the extent that the defendants challenge Gleason's factual assumptions and argue that individual components of the bundle do not exist, are not owned by the University, or are otherwise overvalued, these arguments must be reserved for the trier of fact and go to the weight the trier of fact may give to such evidence. See Avery Dennison, 45 Fed. Appx. at 487 ("The 'facts' challenged by [the defendant] here are not scientific facts to be evaluated under Daubert, but are rather the central questions of liability in the case, which were properly presented to the jury."). The question before the Court is whether Gleason has demonstrated that his methodology of using the concept of "bundling" is sufficiently reliable under Daubert, and the Court is satisfied that he has done so.

The defendants further argue that Gleason's testimony is unreliable because he based his hypothetical royalty rate on licenses that were executed after the hypothetical negotiation date, and because he made no effort to determine whether these licenses were in fact comparable. The Court disagrees with the defendants' contentions. As part of his analysis, Gleason requested that the University provide him with historic licenses negotiated by the University in connection with the following subject areas: (1) medical device technology; (2) medical scanning technology; (3) test data; and (4) co-ownership. Additionally, Gleason conducted other research and reviewed third party sources as to applicable license rates. [Gleason Declaration at ¶2]. With respect to the date range of licenses used, Gleason explains that standard accounting principles recognize that, while the analysis of the hypothetical negotiation must focus on a particular time, comparable licenses may be gathered from other periods. [Id.]. For these reasons, the Court finds that Gleason's methodology in this respect is sufficiently reliable.

Next, the defendants argue that Gleason failed to identify the specific intellectual property that he is supposedly valuing. Specifically, the defendants argue that Gleason cannot identify what the "scanner process" at issue is and that he cannot explain what is contained in the "know-how" that he seeks to value. The defendants also note that Gleason refers to valuing "trade secrets," even though there are no trade secrets at issue in this case.

The Court does not find Gleason's lack of familiarity with the specific technology and related terminology to be fatal to his analysis. With respect to Gleason's reference to "trade secrets," it appears from the Court's review of his report and testimony that Gleason simply used this term interchangeably with "know-how," and accordingly, this lack of precision in terminology does not impact the reliability of his overall analysis. With respect to Gleason's inability to identify the intellectual property, Gleason admittedly does not possess the expertise to identify the particular intellectual property contributions of the University. Rather, his report is premised upon the factual assumption, provided by the University's counsel and other experts, that the claimed intellectual property, *i.e.*, the patents, know-how, and test data, were at least in part owned by the University and that the University is entitled to compensation for the use of this intellectual property by others. The Court finds that Gleason's reliance upon this factual assumption is reasonable, and his valuation of this intellectual property is not invalidated by his lack of expertise in identifying the particular intellectual property at issue.

Finally, the defendants assert that Gleason improperly added value to the royalty by assuming that the defendants would desire an exclusive license. The defendants argue that Gleason did nothing to determine that GE or another competitor would have wanted to license the intellectual property at issue. In support of his opinion that the hypothetical license would have been exclusive,

Gleason cites various internal CTI documents, which express concern over competitors' efforts to develop and market similar technology. The Court finds that Gleason's consideration of these documents to be a reliable basis for his opinion that the hypothetical license would have been an exclusive one. The fact that Gleason did not confirm that GE or another competitor in fact desired to license this intellectual property is an issue that goes more to the weight to be given Gleason's testimony, rather than its admissibility, and the defendants are free to cross-examine Gleason on this issue.

For the foregoing reasons, Defendants' Motion *in Limine* to Exclude the Testimony of Plaintiff's Proposed Expert Mark Gleason [Doc. 81] is **DENIED**.

CONCLUSION

For the foregoing reasons, it is hereby **ORDERED**:

(1) Defendants' Motion to Exclude Expert Testimony Based on Spoliation of Evidence [Doc. 84] is **DENIED**.

(2) Defendants' Motion *in Limine* to Exclude the Testimony of Plaintiff's Proposed Expert Robert Wooldridge [Doc. 77] is **GRANTED IN PART** and **DENIED IN PART**;

(3) Defendants' Motion *in Limine* to Exclude the Testimony of Plaintiff's Proposed Expert Thomas Lewellen [Doc. 79] is **GRANTED IN PART** and **DENIED IN PART**; and

(4) Defendants' Motion *in Limine* to Exclude the Testimony of Plaintiff's Proposed Expert Mark Gleason [Doc. 81] is **DENIED**.

IT IS SO ORDERED.

ENTER:

s/ C. Clifford Shirley, Jr.
United States Magistrate Judge